



CONSENT TO PARTICIPATE

ROCKY MOUNTAIN ■
CANCER GENETICS COALITION
of the
CANCER GENETICS NETWORK

Principal Investigator
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**You are being invited to join a research program called the
Rocky Mountain Cancer Genetics Coalition.
This program is part of the Cancer Genetics Network, sponsored by
the National Cancer Institute,
which is enrolling participants throughout the United States.**

What is the Rocky Mountain Cancer Genetics Coalition?

The Rocky Mountain Cancer Genetics Coalition (local network) is made up of three sites in the intermountain west that are participating in the Cancer Genetics Network. The sites are:

- Huntsman Cancer Institute at the University of Utah
- University of Colorado Cancer Center
- University of New Mexico Epidemiology and Cancer Control

The Huntsman Cancer Institute at the University of Utah will be responsible for collecting and keeping the information you provide to the local network.



What is the Cancer Genetics Network?

The Cancer Genetics Network (national network) is a national effort to develop a resource to help researchers better understand what causes cancer and how to improve its detection, prevention, and treatment. For this project, researchers are most interested in studying families in which there is a history of cancer. Many research studies need more participants than any one cancer research center can enroll. Therefore, the national network is made up of eight major sites, each with several partner locations. Each site will invite people who may be willing to be in future cancer research studies into a network.

Why is there a need for a Cancer Genetics Network?

By combining people from all of the network sites, this national network will provide a way for researchers to increase the number of study participants for certain research projects. This could make it possible for the research to happen more quickly and effectively. The national network will also contribute to cancer research by gathering some basic medical and family history information about each participant. This information will be updated every year and may be useful in answering some basic research questions about cancer and genetics.

Who is being invited into the Rocky Mountain Cancer Genetics Coalition?

You will be invited to be in the local network if:

- You have had breast, ovarian, colon, rectal or prostate cancer; or
- You are closely related to someone who has had one of these cancers.

At the Huntsman Cancer Institute, we hope to enroll 8,000 individuals into the local network.

Who is being enrolled in the national network?

Once you have been enrolled in the local network, we will choose whether to send your information to the national network based upon such factors as a family history of cancer and the age when cancer occurred in your family members. It is possible that information you provide may be used by the local network but may not be sent to the national network.

What will I be asked to do if I join this network?

1. *Complete a questionnaire*

You will be asked to complete a mailed questionnaire that may take about 20 minutes. The questionnaire asks for information about you (such as age, sex, and ethnic background), your medical history, your health habits, and the history of any cancer in your family. In addition, some people who join the local network might be asked to provide contact information about their relatives.

2. *Allow us to contact you for updates*

Each year, the local network will contact you for two reasons:

- To update your information and
- To make sure you are still willing to participate.

3. *Consent to contact you about future research studies*

Information you give to the local network may be used by some researchers for approved research purposes. However, these data will be provided to researchers only after your name has been removed.

Other researchers may need more information, a blood sample, or a sample of tissue from surgery you or one of your relatives have had. For example, a researcher at another cancer center may want to ask you for more information by telephone or letter. Before we give the researcher your name, we will call or write to you and give you more information about that study. You can then let us know if you want to be in that study. If you agree to be in the study, we will ask your permission to give your name to the researcher.

If you are interested in participating in a future study, you will be asked to sign a separate consent form at that time. That means there will be two chances to decide about participating – first when you are asked to give your name to the researcher and then after the researcher has explained the complete study to you.

It is also possible that you might not be contacted about participating in a future research study because you are not eligible for any of the proposed studies.



Photo: Brett Colvin

What benefits will I receive by being in the network?

There are no direct medical benefits that will result from your participating in the network.

One possible benefit of being in the network may be access to information about the latest advances in cancer genetics.

What are the risks of participating?

People sometimes feel anxious or upset when asked questions about their personal or family history of cancer, like those in the basic information questionnaire. It is possible that you might find it disturbing when you are contacted in the future to update information or to determine your interest in participating in a research study.

Although we have made every effort to protect your confidentiality, there may be a risk of loss of confidentiality associated with being a part of a network. In addition, unforeseen risks may occur as a result of your participation.

How is my confidentiality protected?

Every effort will be made to protect your confidentiality. The following measures will be taken to secure the information you provide:

All personal information given to the local network will be kept in locked cabinets and secured computers. Your basic information, including information that can specifically identify you (such as your name, address, or date of birth) will be entered into a secure computer database at the Huntsman Cancer Institute at the University of Utah.

Information that can identify you will be separated from your other information, which will be given a code number. Information, such as age, sex and medical history, may then be sent to the Cancer Genetics Network's national databank at the University of California at Irvine. Information from all participating national network centers will be stored in the national database by *code number only*.

Your information and the code number that links that information to you will be kept at the Huntsman Cancer Institute and will be available *only* to the staff here. In other words, no one outside of the Huntsman Cancer Institute will ever be able to link your name with your information. Because your name and contact information will be on file only at the Huntsman Cancer Institute, our staff will make all future contacts with you, unless you give your permission for someone else to contact you.



Photo: Diana Lim

What else do I need to know?

Voluntary Participation

Your participation in the local network is voluntary. You can choose not to participate in the network. If you sign this form, you agree to give the local network permission to use the information you provide and share it with the national network. The local and national network may keep this information indefinitely and may use it in future research studies for an unlimited period of time.

You are free to withdraw from the local network at any time. If you choose to withdraw, you will still receive the same clinical care you would have otherwise received. If you withdraw, your information will be removed from both the local and national networks. Also, participation in the local network may be stopped by the investigator without your consent.

Financial Costs

You will receive no money for enrolling in the network, nor will you have to pay to be in the network. If you decide to participate in a future research study, there may be costs associated with that study which would be explained to you at that time.

Medical Treatment or Compensation for Injury

In the event you sustain injury resulting from your participation in the research project, the University of Utah can provide to you, without charge, emergency and temporary medical treatment not otherwise covered by your own insurance. If you believe that you have sustained an injury as a result of your participation in this research program, please contact the Office of the Vice President for Research, phone number 801-581-7236. By signing this document, you are not giving up your right to pursue legal action against any and all parties involved with this research, in accordance with the Utah Governmental Immunity Act, Section 63-30-1:63-30-34 Utah Code Ann. 1953 (as amended).

New Information

Sometimes the information that you have given us leads to new discoveries. If we learn something that can help people in our local network, we will share it with you.

Contact Persons

If at any time you have questions or comments about the local network or your rights as a participant, you should contact Julie Shakib, Program Coordinator, at 801-585-7121 or toll free at 877-585-0473.

Institutional Review Board

The University of Utah has a committee called the Institutional Review Board. It is their job to make sure that people are informed about the risks and benefits of a particular research project. If you have questions regarding your rights as a research subject, or if problems arise which you do not feel you can discuss with the Investigator, please contact the Institutional Review Board Office at 801-581-3655.

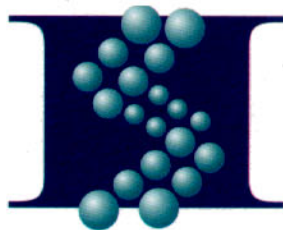
For questions or comments, please contact

Julie Shakib
Program Coordinator

1-801-585-7121 (in Salt Lake)

or

1-877-585-0473 (TOLL FREE)



HUNTSMAN
CANCER INSTITUTE

AT THE UNIVERSITY
OF UTAH



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